AlloSource®

THE BONE & TISSUE STANDARD

July 24, 2000

Ms. Kathy Eberhart
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 North
Rockville, Maryland 20852-1448

Dear Ms. Eberhart:

Attached to this cover letter is a "Position Paper" from AlloSource, to the Agency, with specific regard to the issues of "Minimal Manipulation and Homologous Use" of human bone allografts.

While AlloSource will have representation at the August 2, 2000, meeting between the FDA, AATB and industry representatives, the enclosed is a "position paper" only, we will not be making a presentation at the meeting.

Respectfully,

Audie D. Margrave
Director of Quality Assurance

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A Non-Profit Organization

AlloSource®

THE BONE & TISSUE STANDARD

POSITION PAPER
ON
HUMAN BONE ALLOGRAFT;
MINIMAL MANIPULATION
And
HOMOLOGOUS USE

Introduction

AlloSource, is a human tissue bank located in Denver, Colorado. AlloSource has been processing and distributing safe human allografts for many years to our donor communities. To date AlloSource has processed and distributed hundreds of thousands of allografts that were safe and beneficial to the recipients of these tissues. We distribute allografts to hundreds of hospitals and physicians throughout the United States. AlloSource is accredited by the American Association of Tissue Banks and is registered in the states that require registration. Our facility and staff are dedicated to the safe handling and processing of allografts for the improvement of the quality of life for literally thousands of patients across the United States.

AlloSource offers the following position with regard to the use of processed and pre-shaped human tissue:

1. **The use of donated human allografts has been practiced in this country for almost 50 years, with an incredible history of safety and efficacy.**

2. **The use of processed human bone allografts, with existing regulations, have improved the quality of life for millions of recipients.**

3. **There is clear clinical data that supports the continued use of human bone allografts in orthopedic, dental, and spinal applications, that will be severely and negatively impacted by the proposed restriction of allografts to homologous use.**

4. **Classification of human bone allografts as medical devices would greatly decrease the availability of these products as well as substantially increase the costs of these products to the medical community and the recipients of these products.**

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IMPACT OF PROPOSED MINIMAL MANIPULATION RESTRICITIONS

- **For well over fifty years, tissue processors have been cutting, grinding, sizing and shaping donated human bone into usable configurations for physicians, with strong documented evidence of both safety and efficacy.**

Since World War II, the utilization of processed human bone by physicians has resulted in the improvement in the quality of life of the recipients of these products. These products need to be shaped, cut, ground or threaded in order to effect the intended clinical application and therapy. The use of natural bone versus synthetic or metallic equivalent results in shorter hospital stays, improved healing times and less need for surgical follow up after the surgery.

Tissue processors offer shaped, cut, ground or threaded human bone products to physicians as a matter of convenience to the physicians. The availability of processed tissue in various configurations not only saves the physician time during surgeries, it also results in the recipient not having to spend additional time under the influence, control and negative effects of drugs required during surgery.

The result of minimal manipulation controls will drive many currently available and economical human bone products into being classified as medical devices. This will result in bone products being subjected to unneeded rules and regulations and unwarranted clinical studies which will greatly reduce the availability of these products as well as drive the prices as high or higher than the current synthetic or metal equivalent medical devices.

Lastly, there is no evidence that the current processing methods utilized by tissue processors, or the cutting, shaping, etc. of bone by physicians in an operating room has any detrimental effects on the safety or efficacy of the bone.

IMPACT OF PROPOSED HOMOLOGOUS USE RESTRICTIONS

- **The current utilization and therapies of non-homologous use of tissue facilitates repair of injuries or diseased tissue and bone in a myriad of ways, often times with better strength and longevity than the original tissue or bone.**

The enactment of the proposed homologous use restrictions by the FDA will result in substantial negative impacts upon the tissue industry, surgeons, patients and donated human bone allografts.

Clearly the greatest impact being that of pushing many current bone products into being classified as medical devices. This unto itself is neither warranted or needed in light of the history of the various uses of human bone in the repair of injured or diseased bone in patients. The homologous restrictions will further limit the availability of tissue to the

medical community as well as driving up the subsequent added costs to the medical community.

The next consideration far outweighs the unneeded medical device regulations and the subsequent increased costs of tissue to the medical community.

The homologous use restrictions will result in the unwarranted and useless discarding of donated tissue due to the reduced utilization of tissue by physicians. Homologous use restrictions will result in tissue banks having huge inventories of unused donated human allografts. This will then lead to the destruction of hundreds of thousands of donated human allografts over time, as human bone will does not remain viable indefinitely. The subsequent destruction of donated bone is a violation of the basic premise behind human bone allograft donation, that being that the donated bone will be used in some application for a living patient in need. This gross destruction of donated bone would be a tremendous and ludicrous waste and would have an extremely detrimental impact on the tissue donation efforts in the United States.

It is estimated that the current available therapies and clinical utilization of donated tissue would decrease by more than 90% if the proposed homologous use restrictions become law. The number of patients not receiving needed bone repairs would be in the hundreds of thousands per year. This is both unfathomable as well as inhumane.

SUMMARY

- **The overall effect of the proposed minimal manipulation and homologous use restrictions will result in the unwarranted reclassification of donated human bone allografts as medical devices. This would subsequently result in a huge negative impact upon patient care and health betterment as well as exponentially and bureaucratically increasing the price of processed bone products.**

In summary, AlloSource believes that:

1. Human bone allografts have a long, indisputable history of safety and efficacy.
2. The current tissue banking standards as well as 21 CFR 1270 regulations assure the safe harvesting, processing, packaging and distribution of human bone allografts.
3. The current practices of processing, forming and shaping of human bone allografts for the various surgical indications have been proven has proven safe and effective.
4. The current practices of processing, forming and shaping of human bone allografts by tissue processors and physicians results in enhanced surgical procedures, quicker patient healing times, and improved quality of life for the patients.

5. Further regulating of human bone allografts are unnecessary and would have profound effects on both bone product availability as well as the donation efforts in the United States.

AlloSource strongly recommends that donated human bone allografts remain in its current classification as tissue. Reclassification of human bone allografts to that of medical devices will have serious, negative and detrimental effects upon patient care. Lastly, AlloSource can see no logical or medical rationale for the enactment of such restrictions as minimal manipulation and homologous use.

If the FDA has identified and documented material safety issues that are not addressed by existing regulations, AlloSource would continue to support steps to assure the safe recovery, processing, distribution and use of musculoskeletal allograft in the United States. To the best of our belief and knowledge, there are not any material safety issues that not currently addressed.